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PATENT
P-4815-US1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): CHAIN, Daniel G.

SERIAL NO.: 10/084,380 EXAMINER: P.DUFFY

FILED: February 28, 2002 GROUP ART UNIT: 1645

FOR.: ANTIBODIES WHICH ARE FREE END-SPECIFIC FOR THE
N-TERMINUS OR THE C-TERMINUS OF AN AMYLOID B PEPTIDE,
PHARMACEUTICAL COMPOSITIONS AND METHOD OF USE
THEREOF

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1. ☒ Documents including patents, publications, and other information listed on the attached Form PTO-1449 for consideration by the Examiner;
2. ☐ Form PTO-1449 which lists documents including patents, publications and other information for consideration by the Examiner but in accordance with 37 C.F.R. 1.98(d) does not include those documents which have been previously cited or submitted to the Patent Office in the following prior application U.S. Serial No. _____, filed _____ which is properly identified and relied on.
3. ☐ Other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application.

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search

has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I) ☒ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

II) ☐ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first;

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2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 05-0649.

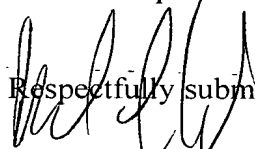
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Respectfully submitted,


Mark S. Cohen
Attorney for Applicant(s)
Registration No. 42,425

Dated: May 30, 2002

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Application Number	09/402,820
Filing Date	October 12, 1999
First Named Inventor	CHAIN, Daniel G.
Group Art Unit	1543
Examiner Name	P. Duffy
Attorney Docket Number	P-4815-US

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Sheet	1	of	4
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AJ	BUSCIGLIO J, ET AL. (1193) "Generation of b-amyloid in the secretory pathway in neuronal and nonneuronal cells" Proc. Natl. Acad. Sci. 90, 2092-2096	<input type="checkbox"/>
	AK	GEGEDDES JW ET AL. (1999) "N-terminus truncated b-amyloid peptides and C-terminus truncated secreted forms of of anyloid precursor protein: distinct roles in the pathogenesis of Alzheimer's disease" Neurobiol of Aging 20, 75-79.	<input type="checkbox"/>
	AL	HAAS C ET AL. (1992) "Amyloid b-peptide is produced by cultured cells during normal metabolism" Nature 359, 322-325	<input type="checkbox"/>
	AM	HAAS C ET AL. (1993) "Cellular processing of β amyloid precursor protein and the genesis of amyloid β -peptide." Cell 75, <1039-1042	<input type="checkbox"/>
	AN	HIGGINS LS ET AL. (1996) "p3 b amyloid peptide has a unique and potentially pathogenic immunohistochemical profile in Alzheimer's disease brain." Am. J. Pathol 149, 585-596	<input type="checkbox"/>
	AO	JOHNSON-WOOD K. ET AL. "Amyloid precursor protein processing and A beta42 deposition in a transgenic mouse model of Alzheimer disease" Proc Natl. Acad. Sci U.S.A. 1997 Feb 18;94 (4): 1550-5	<input type="checkbox"/>
	AP	LALOWSKI M (1996) "The nonamyloidogenic p3 fragment (amyloid β 17-42) is a major constituent of Down's syndrome cerebellar preamyloid." J Biol Chem 271, 33623-31	<input type="checkbox"/>
	AQ	LARNER AJ (1999) "Hypothesis: amyloid b peptides truncated at the N-terminus contribute to the pathogenesis of Alzheimer's disease." Neurobiol. Of Aging 20, 65-69.	<input type="checkbox"/>
	AR	MASTERS CL ET AL. (1985) "Amyloid plaque core protein in Alzheimer's disease and Down syndrome." Proc. Natl. Acad. Sci. 82, 4245-9	<input type="checkbox"/>
	AS	MILLER DL ET AL. (1994) "Peptide compositions of the cerebrovascular and senile plaque core amyloid deposits of Alzheimer's disease." Archives of Biochemistry and Biophysics 301, 41-52	<input type="checkbox"/>
	AT	NASLUND ET AL. (1994) "Relative abundance of Alzheimer A β amyloid peptide variants in Alzheimer disease and normal aging." Proc. Natl. Acad. Sci. USA 91, 8378-8382	<input type="checkbox"/>
	AU	PIKE CJ ET AL. (1995) "Amino-terminal deletions enhance aggregation of β -amyloid peptides in vitro." J Biol Chem 270, 23895-8	<input type="checkbox"/>
	AV	SEUBERT ET AL. (1992) "Isolation and quantification of soluble Alzheimer's β -peptide from biological fluids." Nature 359, 325-327	<input type="checkbox"/>
	AW	VIGO-PELFREY C ET AL. (1993) "Characterization of beta-amyloid peptide from human cerebrospinal fluid." J Neurochem 61, 1965-8	<input type="checkbox"/>
	AX	HANAN, Eilat et al., "Inhibitory effect of monoclonal antibodies on Alzheimer's Beta-amyloid peptide aggregation" INT. J. EXP. CLIN. INVEST., vol 3, pp. 130-133 (1996).	<input type="checkbox"/>
	AY	SOLOMON, Beka et al., "Monoclonal antibodies inhibit in vitro fibrillar aggregation of the Alzheimer Betaamyloid peptide", PROC. NATL. ACAD. SCI. USA, vol. 93, pp 452-455 (1996)	<input type="checkbox"/>

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AZ	SOLOMON, Beka et al., "Disaggregation of Alzheimer Beta-amyloid by site-directed mAb.", PROC. NATL. ACAD. SCI. USA, vol. 94, pp 4109-4112 (1997)														
BA	TSUZUKI et al., "amyloid beta protein in rot soleus muscle in chloroquine-induced myopathy using end-specific antibodies for A beta 40 and A beta 42: immunohistochemical evidence for amyloid beta protein", <u>Neurosci Letters</u> 202 (1-2):77-80 (1995)														
BB	TURNER et al., "Mayloids $\beta 40$ and $\beta 42$ Are Generated Intracellularly in Cultured Human Neurons and Their Secretion Increases with maturation", <u>J Biol Chem</u> 271 (15):8966:8970 (1996)														
BC	YANAGISAWA et al., "Fractionation of Amyloid β protein ($A\beta$) in Alzheimer's Disease and Down's Syndrome Brains: Presence of Membrane-Bound $A\beta$ ", <u>Ann NY Acad Sci</u> 786:184-194 (1996)														
BD	GRAVINA et al., "Amyloid β Protein ($A\beta$) in Alzheimer's Disease Brain: Biochemical and Immunocytochemical Analysis with Antibodies Specific for Forms Ending at $A\beta 40$ or $A\beta 42(43)$ ", <u>J Biol Chem</u> 270 (13): 7013-7016 (1995)														
BE	HARRINGTON et al., "Characterisation of an epitome specific to the neuron-specific isoform of human enolase recognized by a monoclonal antibody raised against a synthetic peptide corresponding to the C-terminus of β A-protein", <u>Biochim Biophys Acta</u> 1158:120-127 (1993)														
BF	HIGGINS et al., "Transgenic Mouse Brain Histopathology Resembles Early Alzheimer's Disease", <u>Ann Neurol</u> 35:598-607 (1994)														
BG	IWATSUBO et al., "Visualization of $A\beta 42$ (43) and $A\beta 40$ in Senile Plaques with End-Specific $A\beta$ Monoclonals: Evidence that an Initially Deposited species is $A\beta 42(43)$ ", <u>Neuron</u> 13:45-53 (1994)														
BH	IWATSUBO et al., "Amyloid β protein ($A\beta$) Deposition: $A\beta 42$ (43) Precedes $A\beta 40$ in Down Syndrome". <u>Ann Neurol</u> 37:294-299 (1995)														
BI	KONIG et al., "Development and Characterization of a Monoclonal Antibody 369. 2B Specific for the Carboxyl-Terminus of the $\beta A4$ Peptide", <u>Ann NY Acad Sci</u> 777:345-355 (1996)														
BJ	MANN et al., "The extent of amyloid deposition in brain in patients with Down's Syndrome does not depend upon the apolipoprotein E genotype", <u>Neurosci Letters</u> 196 (1-2):105-108 (1995)														
BK	MANN et al., "Predominant Deposition of Amyloid $\beta 42$ (43) in Plaques in Cases of Alzheimer's Disease and Hereditary Cerebral Hemorrhage Associated with Mutations in the Amyloid Precursor Protein Gene", <u>Am J Pathol</u> 148 (4):1257-1265 (1996)														
BL	MANN et al., "Amyloid beta protein (Abeta) deposition in chromosome 14-linked Alzheimer's diseases: predominance of Abeta 43 (43)", <u>Ann Neurol</u> 40 (2):149-156 (1996)														
BM	MURPHY et al., "Development of a Monoclonal Antibody Specific for the COOH-Terminal of β -Amyloid 1-42 and Its Immunohistochemical reactivity in Alzheimer's Disease and Related Disorders", <u>Am J Pathol</u> 144 (5):1082-1088 (1994)														
BN	NAKAMURA et al., "Carboxyl end-specific monoclonal antibodies to amyloid beta protein (A beta) subtypes (A beta 40 and A beta 42 (43) differentiate A beta in senile plaques and amyloid angiopathy in brains of aged cynomolgus monkeys." <u>Neurosci Letters</u> 201(2):151-154 (1996)														

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	BO	SAIDO et al., "Spatial Resolution of Fodrin Proteolysis in Postischemic Brain", <u>J Biol Chem</u> 268(33): 25239-25243 (1993)			
	BP	SUZUKI et al., "High Tissue Content of Soluble β 1-40 is Linked to Cerebral Amyloid Angiopathy", <u>Am J Pathol</u> 145 (2):452-460 (1994)			
	BQ	TAMAOKA et al., "Amyloid β protein 1-42/43 ($A\beta$ 1-42/43) in cerebellar diffuse plaques: enzyme-linked immunosorbent assay and immunocytochemical study", <u>Brain Res</u> 679:151-156 (1995)			
	BR	DUERIASSE et al. <u>Bio Techniques</u> , 16 (3): 436-482			
	BS	JOHNSON-WOOD K. ET AL, "Amyloid precursor protein processing and A beta42 deposition in a transgenic mouse model of Alzheimer disease," 1997, <u>Proc Natl Acad Sci U S A</u> Feb 18;94(4), pp 1550-5.			

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